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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,854	01/17/2001	Samuel G. Armato III	200655US20	4576
22850	22850 7590 01/13/2005		EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET			BHATNAGAR, ANAND P	
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			2623	
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)									
	09/760,854	ARMATO ET AL.									
Office Action Summary	Examiner	Art Unit									
	Anand Bhatnagar	2623									
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply											
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	i6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	ely filed  will be considered timely. he mailing date of this communication.  0 (35 U.S.C. § 133).									
Status											
1) Responsive to communication(s) filed on <u>24 June 2004</u> .											
2a)⊠ This action is <b>FINAL</b> . 2b)□ This	∑ This action is FINAL. 2b) This action is non-final.										
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.											
Disposition of Claims											
4)⊠ Claim(s) <u>1-51</u> is/are pending in the application.											
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.										
5)⊠ Claim(s) <u>8-17,25-28 and 42-45</u> is/are allowed. 6)⊠ Claim(s) <u>1,2,4-7,18,19,21-24,29-36,38-41 and 46-51</u> is/are rejected. 7)⊠ Claim(s) <u>3,20 and 37</u> is/are objected to.											
						8) Claim(s) are subject to restriction and/or election requirement.					
						Application Papers					
9)☐ The specification is objected to by the Examiner.											
10)⊠ The drawing(s) filed on <u>01/17/01</u> is/are: a)□ accepted or b)□ objected to by the Examiner.											
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).											
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).											
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.											
Priority under 35 U.S.C. § 119											
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).											
a) All b) Some * c) None of:											
1. Certified copies of the priority documents have been received.											
2. Certified copies of the priority documents have been received in Application No											
3. Copies of the certified copies of the priority documents have been received in this National Stage											
application from the International Bureau (PCT Rule 17.2(a)).											
* See the attached detailed Office action for a list of the certified copies not received.											
Attachment(s)											
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)											
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date										
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal Pa	atent Application (PTO-152)									

# Response to Arguments

1. Applicant's amendment filed on 06/24/04 has been entered and made of record.

- 2. Applicant has amended claims 1-3, 6, 18-20, 23, 35-37, and 40. Currently claims 1-51 are pending.
- Applicant's in essence argues, on page 18 to middle of page 20 for claims 1, 18, and 35, that the prior art of Giger et al. (U.S. patent 5,881,124) and Vining (U.S. patent 6,272,366 B1) do not teach the feature of "performing region growing from another seed point located in a subsequent cross-sectional thoracic image to segment the major airway within the subsequent cross-sectional thoracic image." This is a newly added feature to the claims and will be addressed below in the action.

Regarding claim 2, applicant argues that the office action does not give why someone skilled in the art would determine the "center of mass." As explained in the office action the process dilation/growing when performed is usually performed where a seed is placed in the center of the object and region growing taking place outward from this region. The center of the object is usually the center of mass of the object, especially in a uniformly shaped object.

Applicant's argument (bottom of page 20 to top of page 21), for claim 3, is persuasive and is withdrawing the rejection for this claim. Claim 20 and 37 have similar limitations as claim 3, therefore the rejections to these claims are also withdrawn.

Regarding claims 6, 23, and 40: Applicant argues (bottom of page 21 to bottom of page 22) that the prior art of Giger et al. does not disclose to identify the fusion of the, identify the cleft point on the lung contour, etc. based on gray level values and applicant also argues that the examiner is using hindsight to construct applicant's instant invention. Examiner disagrees. Examiner is not using hindsight since the prior art of Giger et al. discloses to obtain the boundaries of the lungs as well as for the thorax using gray scale levels (Giger et al.; fig. 1, col. 3 lines 50-67, and col. 4 lines 41-50). Giger et al. does not state which boundaries nor points on the boundaries to identify but any one skilled in the art can modify the system to look for specific point/regions/boundaries on the lungs and/or the thorax that are of interest based on Giger's disclosure. Further applicant does not give any kind of reason why his identification of boundaries and/or points on the boundaries of the lungs, of applicant's instant invention, is more advantageous and different then the identification process, i.e. the steps in identifying not which boundaries in a specific order, of the prior art of Giger et al.

Regarding claims 12, 29, and 46: Applicant argues (page 23) that no motivation is given for why the diaphragm would have been identified. The motivation is a basic one and it is to identify the bottom region/boundary of the lungs. For example, in the case of a person having pneumonia, the diaphragm is used to locate the costophrenic regions of the lungs because this is the region that gets most affected due to fluid build up. Also identifying landmarks, such as ribs, diaphragm, vertebrae, etc. gives the approximate location/level of the image

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of the lungs/thorax being analyzed and if an abnormality exists it can be easily identified at what region/level it is at.

Regarding claims 8, 11, 25, 28, 42, and 45: Applicant's arguments (pages 23-25) are persuasive and the rejection to these claims are withdrawn. Examiner refers to the rejection below.

### **DETAILED ACTION**

# Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
  - A.) Claims 1, 2, 4-7, 18, 19, 21-24, 29, 31, 32, 35, 36, 38-41, 46, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (U.S. patent 5,881,124) and Vining (U.S. patent 6,272,366 B1).

Regarding claims 1, 18, and 35: Giger et al. discloses a method for the automated segmentation of lung regions in thoracic images (Giger et al.; fig. 1 and col. 1 lines 7-11) comprising:

acquiring image data representative of a cross-sectional thoracic image (Giger et al.; figs. 1 and 2A and col. 3 lines 66 and 67, and col. 4 lines 1-3);

segmenting the lung regions (Giger et al.; fig. 1 and col. 3 lines 55-58).

Giger et al. discloses to obtain a cross-sectional image of the thorax from which the lung boundaries are detected. Giger et al. does not teach to establish a seed in a major airway and to grow the seed and then extract the major airway. Vining teaches to grow seed and to grow the region of a selected organ in order to extract this specific organ as a region of interest, such as the tracheobronchial airways (Vining; fig. 15 and col. 3 lines 5-10, 23-30, and 54-56). It would have been obvious to one skilled in the art to combine the teaching of Vining to that of Giger et al. because they are analogous in obtaining and processing images of anatomical structures to analyze these regions for presence of a pathological abnormality. One in the art would have been motivated to incorporate the teaching of Vining into the system of Giger et al. in order to have a reliable efficient method for examining the tracheobronchial and/or colon of a patient to detect early cancer (Vining; col. 2 lines 13-15).

Giger et al. discloses to identify regions/boundaries of the lungs and the thorax. Giger et al. does not teach the feature of "performing region growing from another seed point located in a subsequent cross-sectional thoracic image to segment the major airway within the subsequent cross-sectional thoracic image." Vining teaches the step of region growing use a seed point in a part of a region of an organ in an image (Vining; fig. 15 and col. 3 lines 5-10, 23-30, and 54-56). It would have been obvious to one skilled in the art to combine the teaching of Vining to that of Giger et al. because they are analogous in obtaining and

processing images of anatomical structures to analyze these regions for presence of a pathological abnormality. One in the art would have been motivated to incorporate the teaching of Vining, modified for a second region seeding and growing in any image or all the images obtained of the organ of interest or within the same image itself, into the system of Giger et al. in order to have a reliable efficient method for examining the tracheobronchial and/or colon of a patient to detect early cancer (Vining; col. 2 lines 13-15).

Regarding claims 2, 19, and 36: The method further comprising:

determining a first pixel corresponding to a center of mass of the segmented major airway (Vining; col. 3 lines 23-30, wherein the seed point is planted inside the lumen of the organ. It is obvious to one skilled in the art for a dilation process in image processing using a seed point is usually performed wherein the seed point is placed in the center of the region of interest.).

Regarding claims 4, 21, and 38: The method wherein the major airway is the trachea (Vining; col. 3 lines 53-56). The obvious and motivation are the same as claim 1 above.

Regarding claims 5, 22, and 39. The method wherein the major airway is one of the first main stem bronchus and the second main stem bronchus (Vining; col. 3 lines 53-56). The obvious and motivation are the same as claim 1 above.

Regarding claims 6, 23, and 40: A method for the automated segmentation of lung regions in thoracic images (Giger et al.; fig. 1 and col. 1 lines 7-11), comprising:

generating at least one lung contour to segment the lung regions a cross-sectional thoracic image (Giger et al.; fig. 1 and col.3 lines 53-60 where the thorax and lung boundaries are detected).

Giger et al. discloses to obtain images of the thorax containing the lungs wherein a gray scale analysis is performed on the images in order to detect any pathological abnormalities that may be present (col. 3 lines 53-63). Giger et al. obtains multiple computed tomographic images of the lungs. Giger does not discloses to analyze the images for specific anatomical locations in the images, such as the fusion of the lungs, the cleft point, the anterior junction line, etc. It would have been obvious to one skilled in the art to modify the system so that any number of anatomical points of the lungs (such as the cleft, the costophrenic angle, anterior junction line, the points where the lungs are fused together, etc.) as well as any neighboring anatomical structures (such as the diaphragm, heart, esophagus, etc.) may be analyzed using the gray scale of the images, taken into consideration into the data of the image, or suppressed/extracted from the image to enhance the region of interest in the images.

Regarding claims 7, 24, and 41: It is rejected for the same reason as claim 6, 23, and 40 above and for the following limitation of: identifying, within each row of pixels that includes a pixel of the line segment with the highest average gray level value, a pixel with the highest gray level within a predetermined distance of the line segment with the highest average gray level value; and

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including within the anterior junction line the pixels identified as having the highest gray level in each row.

It is obvious to one skilled in the art that once the gray scale of all the images are obtained then this data can be analyzed for pixel intensities and their respective locations (the x-y positions, which is equivalent to the row and columns) in each image.

Regarding claims 12, 14, 15, 29, 31, 32, 46, 48 and 49: They are rejected for the same reasons as claims 1, 18, and 35 and claims 6,23, and 40 combined.

Regarding claims 35-41, 46, 48, and 49: For the limitation of a computer readable medium (col. 12 lines 32-34).

B.) Claims 30, 33, 34, 47, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armato et al. (WO 99/42031) in view of Giger et al. (U.S. patent 5,881,124).

Regarding claims 30, 33, 34, 47, 50, and 51: A method for the automated segmentation of lung regions in thoracic images, comprising:

Armato et al. discloses acquiring image data representative of a thoracic image (Armato et al.; page 4 bottom half of page, where the image of the Thorax is obtained and the lungs counters detected);

generating initial lung contours to segment the lung regions (Armato et al.; page 4 bottom half of page, where the image of the Thorax is obtained and the lungs counters detected);

refining the lung contours by applying a rolling ball filter to the initial lung contours to identify indentations along the initial lung contours (Armato et al.; fig. 1 elements S7 and S8, fig. 11, page 9 lines 1-6, and page 14 bottom of the page the description of Fig.11).

Armato et al. discloses to obtain images of the lungs and to smooth the contours in the image using a smoothing and a rolling ball filter. Armato et al. does not teach to obtain a cross-sectional image of the thorax nor teaches to determine the characteristics of the indentations and what causes the indentations, such as the diaphragm. Giger et al.teaches to obtain a cross-sectional image of a patient and detect the lungs in the image to analyze for any presence of an abnormality within the lungs (Giger et al.; fig. 1 and col. 3 lines 50-60). It would have been obvious to one skilled in the art to combine the teaching of Giger et al. to that of Armato et al. because they are analogous in imaging the lungs for detecting any presence of abnormalities. One in the art would have been motivated to incorporate the teaching of Giger et al. to that of Armato et al. in order to have a system to allow the various lesions to be detected, they must be analyzed at different threshold levels because they have different sizes and composition (Giger et al.; col. 2 lines 29-34).

As for the limitation of detecting the characteristics/geometrics of the holes/indentations and the cause of these holes/indentations. It would have been obvious to one skilled in the art to first analyze these features in order to know where the indentations are present, their respective sizes and which contours in

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the image contain these indentations such as the diaphragm so that the algorithm is only applied to these locations/contours, and if needed, the algorithm adjusted for the different sizes of indentations to make the system more efficient.

Regarding claims 47, 50 and 51: For the limitation of a computer readable medium (col. 12 lines 32-34).

# Allowable Subject Matter

- 5. Claims 8-17, 25-28, and 42-45 are allowed.
- 6. Claims 3, 20, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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### **Contact Information**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand Bhatnagar whose telephone number is (703) 306-5914, whose supervisor is Amelia Au whose number is 703-308-6604. group fax is 703-872-9306, and Tech center 2600 customer service office number is 703-306-0377.

Anand Bhatnagar

Art Unit 2623 January 9, 2005

SAMIR AHMED